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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,434

04/16/2004

Joseph Levy

LEVY=18A

9886

1444 7590 12/27/2010

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

12/27/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/825,434

Applicant(s)

LEVY ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 15 December 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1615

Continuation of 11. does NOT place the application in condition for allowance because: Applicant argued, "Jackson requires many active ingredients, not only what is called for in Applicant's claims. Jackson does not teach or suggest a composition having as active ingredients only (1) at least one of phytoestrogen and (2) a combination of carotenoids comprising lycopene and at least one of phytoene and phytofluene".

These arguments have been considered but were not persuasive. Regarding the claim limitation of claim 19, that the dosage form is one "having as active ingredients only at least one phytoestrogen and at least one carotenoid", it is noted that Jackson includes some additional elements in their composition, besides from the phytoestrogens and carotenoids, such as vitamins and minerals. However, a review of the instant specification demonstrates that Applicant's themselves permit the inclusion of additional active ingredients, in addition to the phytoestrogens and carotenoids, such as the additional hormones as shown on p. 12, lower half of 2nd paragraph. Thus, it cannot be seen as to how the additional vitamins and minerals of Jackson would be adversary to the instant formulation, since Applicants explicitly permit the inclusion of additional actives in their formulation. No closed-ended (i.e., "consisting of") claim language has been presented which would exclude the additional vitamins and minerals of Jackson. Consequently, Jackson remains relevant for its teachings.

Applicant argued, "One reference (Jackson) discloses compositions containing many active ingredients, whereas the number of active ingredients is limited in Applicant's claims and the other reference (Schlipalius) teaches a composition containing only active ingredient; neither reference requires only two types of active ingredients".

This argument was not persuasive. The instant invention is not limited exclusively to the use of only two components or two types of active ingredients. The claim language presented does not preclude the additional vitamins/minerals of Jackson nor have Applicants established that the inclusion of Jackson's additional components would provide for any detrimental effects on the composition.

Applicant's argument that "neither reference recognizes the importance of the utilization of the two types of active ingredients required or what the effect might be of the use of just these two types of components" was not persuasive.

The prior art (Jackson) explicitly teaches methods comprising once daily administration of a composition comprising a physiologically effective amount of phytoestrogens in combination with mixed carotenoids having non-provitamin A activity, such as lycopene and lutein (see column 1, lines 4-10); (col. 4, line 39 – col. 5, line 14); (col. 6, line 63 – col. 7, line 25) and Table 1 at column 10. Jackson thus teaches co-administration of phytoestrogens with carotenoids, the same process step employed by Applicant. The art is well aware of co-administration of phytoestrogens with carotenoids to yield beneficial results. Since the art teaches methods, steps and features as claimed by Applicant and recognizes the use of active ingredients (phytoestrogens, carotenoids, etc.), the significance of the effects and results of these ingredients would be necessarily attained therein.

With regards to Applicants disputing of the Examiner's comments regarding claim 23, stating, "claim 23 is not and was not pending during the time the Final Rejection was made" is noted. The inclusion of this statement was made based on an inadvertency and was not intended to be included and does not apply, as claim 23 is not currently pending and has been cancelled.

Applicant argued, "To say that the language of the claims is not closed and/or one must use 'consisting of' to provide closed language, makes no sense in view of the express use of the word 'only' in Applicant's claims."

This argument was not persuasive. While the term "only" is included in Applicant's claims with respect to the unit dosage form, it remains the position of the Examiner that no detrimental effects have been established based on the inclusion of the additional vitamins/minerals disclosed by Jackson. Note also that the instant claims contain the term "comprising" and "having" which equates with open-ended claim language. Nonetheless, Applicant's themselves permit additional components/actives based on the instant specification, thus it cannot be seen as to why the additional agents of the art would be adversary, particularly in view of the fact that the additional components/actives are not precluded by Applicants, as evidenced in the specification.

Applicant argued, "The Examiner brushes aside the required active ingredients of Jackson, and emphasizes the optional ingredients."

This argument was not persuasive. The Jackson reference is relevant and sufficient for all that it suggests and teaches to one of ordinary skill in the art. The Examiner is not denying the required elements of Jackson, but is taking the position that the additional ingredients are not determined to be detrimental. Nor have Applicant's established any superior or unexpected results based on the components claimed (phytoestrogens, carotenoids) versus the formulations and methods of the art.

Applicant argued regarding the Examiner's comments on page 7 of the Action stating, "The Examiner's arguments appear to be based on the assumption that the Applicant's claimed method is not novel, i.e., it is anticipated by Jackson, but there is no rejection under 102. The fact that something may be inherent does not make it obvious."

This argument was not convincing since a careful reading of the comments on page 7 indicate that the Examiner is merely arguing the particular properties of an ingredient to be an inherent feature. The references recognize the use of the same component -i.e., phytoestrogens, thus, it would be reasonably expected that the same properties and characteristics would be imparted by the use of the same ingredient. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Applicant argued, "The disclosure of Schlipalius concerning combinations of carotenoids is only very general and constitutes a basket or shotgun disclosure." This argument was not deemed persuasive since the reference is clearly suggestive of carotenoids that include lycopene, phytoene, phytofluene and mixtures thereof (see col. 3, lines 10-19 and claim 10). Hence, one of ordinary skill in the art would be reasonably motivated to employ any combination of carotenoids from those disclosed by Schlipalius, including the combination being presently claimed, namely, the combination of lycopene with either phytoene and/or phytofluene. The reference vividly suggests that mixtures of carotenoids can be used and thus one would be able to vary the particular combination of carotenoids based on the intended outcome or desired result. Further for the reasons advanced in the Final Office Action, Applicant's arguments were not held persuasive.